IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	**CRIMINAL NO. 20-_____**
		DATE FILED: _____
v.	:	
		VIOLATIONS:
	:	**18 U.S.C. § 1343 (wire fraud – 1 count)**
JONATHAN NYCE		**18 U.S.C. §§ 331(a), 331(k), 352(o), and**
	:	**333(a)(2) (misbranded drugs - 4 counts)**
		Notice of Forfeiture

INDICTMENT

COUNT ONE

THE GRAND JURY CHARGES THAT:

At all times relevant to this indictment:

The Food and Drug Administration

1. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the American public by enforcing the Food, Drug and Cosmetic Act ("FDCA"). One main purpose of the FDCA was to ensure that drugs sold for administration to animals were safe, effective, and bore labeling containing only truthful and non-misleading information, and directions adequate to use the drug safely and for all the purposes for which it was intended. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all animal drugs introduced, delivered, and caused to be introduced or delivered in interstate commerce.

2. Under the FDCA, upon first engaging in the manufacture, preparation, propagation, compounding, or processing of any drugs, every person was required to

immediately register his name, place of business, and all such establishments owned or operated by such person. 21 U.S.C. § 360(c). The terms "manufacture, preparation, propagation, compounding, or processing" included repackaging or otherwise changing the container, wrapper, or labeling of any drug during the time between the original manufacture and the final sale to the ultimate consumer or user. 21 U.S.C. § 360(a)(1).

3. Under the FDCA, the term "label" was defined as a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was broader, and included all labels and other written, printed, or graphic matter upon any article, including drugs, or on any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

4. Under the FDCA, drugs were defined as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, 21 U.S.C. § 321(g)(1)(B); articles intended to affect the structure or function of the body of man or other animals, 21 U.S.C. § 321(g)(1)(C); and articles intended for use as components of other drugs. 21 U.S.C. § 321(g)(1)(D).

5. Under the FDCA, the introduction, delivery for introduction, and causing the introduction or delivery for introduction into interstate commerce of a drug that was misbranded was prohibited. 21 U.S.C. § 331(a).

6. A drug was misbranded if, among other things, it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered with the Secretary of Health and Human Services pursuant to 21 U.S.C. § 360 (21 U.S.C. § 352(o)).

7. Under the FDCA, all new animal drugs are considered unsafe unless the FDA received and approved an application which showed, among other things, that the new animal drug was safe and effective for use, a full list of the articles used as components of the drug, and a full description of the facilities and methods used in manufacturing the drug. 21 U.S.C. §§ 360b(a) and (b).

8. Under the FDCA, a person wishing to conduct clinical trials on a new animal drug must, among other requirements, submit a "Notice of Claimed Investigational Exemption for a New Animal Drug" to the FDA, to legally administer the unapproved new drug to the animals that are the subjects of the clinical trial. This notice must include the identity of the new drug, all labeling and other pertinent information, and the identity and address of each clinical investigator. 21 C.F.R. § 511.1(b).

9. Under the FDCA, the sponsor of a new animal drug involved in clinical investigations may not commercially distribute or test-market the new animal drug until a new animal drug application was approved by the FDA. 21 C.F.R. § 511.1(b)(8)(v).

The Parties

10. "CanineCare.us" ("Canine Care") was a Pennsylvania corporation incorporated on or about September 7, 2012. Canine Care marketed and sold products to treat and cure cancer in dogs through the website www.caninecare.us.

11. "Advanced Canine Genetic Testing, LLC" ("ACGT") was a Pennsylvania corporation incorporated on or about November 21, 2014. The principal office location was 399 Arcola Road, Suite 105, Collegeville, Pennsylvania 19426. ACGT marketed and sold products to treat and cure cancer in dogs through the website www.acgt.us.

12. "Canine Advanced Genetic Testing" ("CAGT") was a Pennsylvania company that marketed and sold products to treat and cure cancer in dogs through the website www.cagt.us.

13. Defendant JONATHAN NYCE identified himself at various times as the "CEO and Chief Scientific Officer" of Canine Care and was the registrant of the www.caninecare.us, www.acgt.us, and www.cagt.us websites.

14. C.H. was the owner of a dog that was diagnosed with cancer.

The Drugs

15. "Tumexal" was a drug created by defendant JONATHAN NYCE consisting of a mixture of a hormone called DHEA and other substances. Tumexal was not approved by the FDA.

16. "Naturasone" was a drug created by defendant JONATHAN NYCE consisting of a mixture of DHEA and other substances. Naturasone was not approved by the FDA.

The Warnings

17. On or about October 23, 2014, the FDA sent defendant JONATHAN NYCE a "warning letter" which stated, among other things, that Tumexal and his other products were unapproved new animal drugs which were not generally recognized as safe among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs. The FDA warned NYCE that his marketing of these drugs violated the FDCA.

18. On or about December 11, 2014, the FDA again sent defendant JONATHAN NYCE a letter which requested that NYCE stop marketing his products and warning him that

continued marketing of Tumexal and other unapproved animal drugs would result in enforcement action.

THE SCHEME TO DEFRAUD

19. From in or about September 2012 to at least on or about June 2, 2016 in the Eastern District of Pennsylvania, and elsewhere, defendant

JONATHAN NYCE

devised and intended to devise a scheme to defraud pet owners and to obtain money from those owners by selling them drugs that purported to cure cancer in dogs.

20. It was the object of the scheme described in paragraph 19 for defendant JONATHAN NYCE to unlawfully enrich himself by fraudulently obtaining thousands of dollars in the form of payments from C.H. and others who sought to treat their dying pets.

MANNER AND MEANS

It was part of the scheme that:

21. Defendant JONATHAN NYCE created and maintained various websites to market and sell Tumexal and Naturasone, among other drugs, over the internet. These websites included www.caninecare.us, www.acgt.us, and www.cagt.us. The websites made numerous false and fraudulent claims regarding the safety and efficacy of Tumexal and Naturasone, including statements that, "Tumexal is effective against a wide variety of cancers," and, "In fact, Tumexal will almost always restore a cancer-stricken dog's appetite, spirit and energy!"

22. Defendant JONATHAN NYCE created various promotional materials, including PowerPoint presentations, articles submitted to online publications, and other documents which made false and fraudulent claims regarding the safety and efficacy of his drugs. Some of these

promotional materials, among other claims, falsely stated defendant NYCE's research was "funded in part by the U.S. Food and Drug Administration."

23. Defendant JONATHAN NYCE often spoke over the telephone or corresponded over email with prospective customers. During these conversations, defendant NYCE made similar false and fraudulent claims regarding the safety and efficacy of his drugs.

24. Defendant JONATHAN NYCE falsely told prospective customers that he would develop individualized treatments specifically formulated to treat their pet's cancer.

25. Defendant JONATHAN NYCE attempted to justify marketing his drugs without FDA approval be falsely representing that the dogs were part of clinical trials, but defendant NYCE never obtained an Investigational Exemption from the FDA and did not meet regulatory requirements for conducting a clinical trial.

26. Defendant JONATHAN NYCE told prospective customers their pets would be part of clinical trials and that they must pay him hundreds or thousands of dollars to participate in clinical trials for his products, contrary to the regulatory prohibition on commercial distribution of new animal drugs that were in clinical trial and not approved by the FDA.

27. Defendant JONATHAN NYCE used various online electronic payment services such as PayPal.com to accept payment for orders made by pet owners. The defendant periodically transferred funds from the accounts and other online sources to various bank accounts he controlled. Defendant JONATHAN NYCE used these funds to pay suppliers, to continue business operations, and for his own personal benefit.

28. Defendant JONATHAN NYCE obtained bulk ingredients from various sources, which he then blended together at his manufacturing facility located at 399 Arcola Road in Collegeville, Pennsylvania.

29. Defendant JONATHAN NYCE shipped Tumexal, Naturasone, and other products throughout the United States using the United States Postal Service and other common carriers.

30. After receiving the FDA warning letters, defendant JONATHAN NYCE removed certain claims from his websites and disabled the online ordering system. However NYCE continued to market his drugs and accept orders and payment from interested pet owners via email and telephone.

31. In or about October 2015, in Collegeville, in the Eastern District of Pennsylvania, and elsewhere, defendant

JONATHAN NYCE,

for the purpose of executing the scheme described above, caused to be transmitted by means of wire communication in interstate commerce a payment of approximately $5,139.50 from C.H.

In violation of Title 18, United States Code, Section 1343.

COUNTS TWO AND THREE
(Misbranded Drugs)

THE GRAND JURY CHARGES FURTHER THAT:

1. Paragraphs 1 through 18 of the General Allegations section and 21 through 30 of the Manner and Means section of Count One of this Indictment are incorporated here.

2. On or about the dates below, in the Eastern District of Pennsylvania, and elsewhere, defendant

JONATHAN NYCE

with the intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce, animal drugs that were misbranded, contrary to the provisions of Title 21, United States Code, Section 352(o), in that the drugs were manufactured in an establishment that was not registered with the Secretary of Health and Human Services, as required under Title 21, United States Code, Section 360:

Count	Date	Description	Drugs
2	August 2015	Shipment from Pennsylvania received by C.H. in Illinois	Naturasone B and Naturasone C
3	October 2015	Shipment from Pennsylvania received by C.H. in Illinois	CAGT-AEM

In violation of Title 21, United States Code, Sections 331(a), 352(o), and 333(a)(2).

COUNTS FOUR AND FIVE
(Misbranded Drugs)

THE GRAND JURY CHARGES FURTHER THAT:

1. Paragraphs 1 through 18 of the General Allegations section and 21 through 30 of the Manner and Means section of Count One of this Indictment are incorporated here.

2. On or about the dates below, in the Eastern District of Pennsylvania, and elsewhere, defendant

JONATHAN NYCE

with the intent to defraud and mislead, caused an act to be done with respect to a drug, while such drug was held for sale, after components of the drug were shipped in interstate commerce, which act resulted in the drug being misbranded contrary to Title 21, United States Code, Section 352(o), in that the drugs were manufactured in an establishment that was not registered with the Secretary of Health and Human Services, as required under Title 21, United States Code, Section 360:

Count	Date	Description	Drugs
4	August 24, 2015	Controlled purchase made by an FDA-OCI Special Agent	Naturasone A and Naturasone B
5	November 2, 2015	Controlled purchase made by an FDA-OCI Special Agent	Naturasone A and Naturasone B

In violation of Title 21, United States Code, Sections 331(k), 352(o), and 333(a)(2).

NOTICE OF FORFEITURE

THE GRAND JURY CHARGES THAT:

1. As a result of the violations of Title 18, United States Code, Section 1343, set forth in Count One of this Indictment, defendant

JONATHAN NYCE

shall forfeit to the United States of America any property, real or personal, that constitutes or is derived from proceeds traceable to the commission of such offense.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 28, United States Code, Section 2461(c), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant(s) up to the value of the property subject to forfeiture.

All pursuant to Title 28, United States Code, Section 2461(c), and Title 18, United States Code, Section 981(a)(1)(C).

A TRUE BILL:

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GRAND JURY FOREPERSON

for **William M. McSwain**
United States Attorney